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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,728	12/28/2000	Akihiro Umezawa	766.43	6784

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 08/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/749,728

Applicant(s)

UMEZAWA ET AL.

Examiner

Joseph T. Woitach

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).


4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 1,6-19,21-28,38,39,41,43 and 44.
- Claim(s) withdrawn from consideration: 47-63 and 78-91.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____


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Continuation of 3. NOTE: The proposed amendments change the scope of the claims requiring new considerations and possibly new rejections. For example the scope from any cell meeting the functional requirements to one that is specifically obtained from bone marrow would require a new consideration and possible rejections under 35 USC 102/103 and 112, first paragraph for the ability and/or sufficient guidance for 'obtaining' such a cell from this source from any animal.

Continuation of 11. does NOT place the application in condition for allowance because: To the extent that Applicants' remarks apply to the instant claims, Applicants argue that the new matter rejection is not well understood and argue that such language is supported throughout the specification. This is not found persuasive. Applicants have not pointed to the literal support for such an embodiment, and while Examiner would agree there is general support for the pluripotency of stem cell, there is no guidance nor support for selecting a cell that has a specific capability of differentiating into only two cell types. This limitation implies that there are cell types that can be distinguished from multipotent by their ability to differentiate into a selective number of cell types, and implies the guidance for choosing those two cell types. With respect to enablement, Applicants argue that it would not require undue experimentation and that a declaration will be filed if the position is maintained by the office. This is not found persuasive because it is not the nature of the experiments that is in question, rather the empirical nature that is required. The claims encompass a cell with specific types of functional characteristics from a specific source, however the guidance in the specification only provides general guidance and reduction to practice of a transformed cell line from the mouse, without any specific guidance for obtaining the breadth of the claim. As indicated previously, the primary structural limitation of the cell as set forth in the claims is the absence of cell surface markers, no means for positively selecting the specific cell claimed, nor evidence that the transformed cell type reduced to practice exists in the bone marrow or that the characterization of the mouse would extend to other species encompassed by the claims. Given the limited and general guidance, the skilled artisan is left to establish methodology to obtain the cell as claimed wherein the methodology must be established for different species and empirically tested to validate the methods to establish that such a cell type exists. With regard to the rejections made under 35 USC 112, second paragraph and 102, the rejection are maintained because the amendments have not been entered. To the extent they apply to the instant claims, it is noted again that the claims are given their broadest reasonable interpretation and that a claimed cell that meets the limitations set forth in the claim would anticipate the claim regardless of the source from which it is obtained. Unless the claims and/or the specification provides characteristics/evidence that cells are different from those disclosed in the art, without a lab the office is left to maintain that meeting the characteristics set forth in the claim a cell from any source anticipates the claim.